REMARKS

Claims 1-28 are pending in the present application. Claims 1, 2, 4, 6, 8, 9, 11, 14, 15, 17, 19, 21 and 24 are amended herein. Claims 12 and 20 are canceled without prejudice to Applicant's right to prosecute the subject matter of this claim in a related application. Claims 1, 2, 4, 6, 8, 9, 11, 13-15, 17-19, 21 and 24 are amended. Support for the amendment to claim 1 is found in the specification at least at page 4, lines 17-18; page 17, lines 11-18, 20-22; and page 20, lines 1-25, and in originally-filed claim 12. Support for the amendment to claims 11, 13 and 24 is found in the specification at least at page 20, lines 6-10. Thus, the amendments introduce no new matter. Upon entry of the present Amendment, claims 1-11 and 13-28 will be pending.

Claim Objections

The Examiner has objected to claim 2 because claim 2 depends from itself. Claim 2 has been amended to depend from claim 1.

The Examiner objects to claim 4 because it contains the sentence fragment "cord blood stem cells." This sentence fragment has been deleted.

The Examiner objects to claim 11 as being of improper dependent form. Claim 11 has been amended to recite "3 x 10^{10} total nucleated cells" rather than "5 x 10^{9} total nucleated cells," and thus is properly dependent from claim 1.

Applicant submits that these amendments obviate the Examiner's objections to these claims, and respectfully requests that the Examiner withdraw the objections.

The Rejections Under 35 U.S.C. § 112, Second Paragraph Should Be Withdrawn

The Examiner has rejected claims 1-9 and 11-28 under 35 U.S.C. § 112, second paragraph as indefinite in its recitation of "'[a] method of treating a patient in need thereof' without particularly pointing out what exactly is needed by the patient . . ." (Office Action, page 2.) Applicant respectfully traverses.

Applicant has amended claim 1 to recite "[a] method of treating an individual comprising administration of a composition. . . wherein said administration delivers at least 1 x 10^{10} total nucleated cells, or at least 1 x 10^{9} stem cells, to an individual in need of said administration." This amendment clarifies that the recited individual is one in need of treatment with the recited cord blood or cord blood-derived stem cells. Applicant respectfully submits that the claim as amended is definite, and requests that the examiner remove the rejection of claim 1 on this basis. As the rejection on this basis of claims 2-9 and 11-28 was predicated on the Examiner's finding of indefiniteness of claim 1, Applicant

requests that the Examiner withdraw the rejection of claims 2-9 and 11-28 on this basis, as well.

The Examiner has additionally rejected claims 17 and 21 under 35 U.S.C. § 112, second paragraph as indefinite in the recitation in claim 17 of "said disease, disorder or condition" in line 1, and in claim 21 of "said condition" because the quoted phrases lack antecedent basis. The quoted language has been deleted from claims 17 and 21, and claims 17 and 21 have been amended to conform to amended claim 1. As amended, claim 1 provides sufficient antecedent basis for claims 17 and 21. Applicant requests that the Examiner withdraw the rejection of claims 17 and 21 on this basis.

The Double Patenting Rejections

The Examiner has provisionally rejected claims 1-28 under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claims 20, 21, 25-28, 34-47, 50, 54, 57, 58 and 62-82 of copending application no. 10/366,671 ("the '671 application"). Applicant requests that this rejection be held in abeyance until such time as one set of claims is deemed allowable.

The Rejection Under 35 U.S.C. § 102(b) Should Be Withdrawn

The Examiner has rejected claims 1-10 and 14-28 under 35 U.S.C. § 102(b) as anticipated by Boyse *et al.*, U.S. Patent No. 5,004,681 ("Boyse"). Applicant respectfully traverses.

For a reference to anticipate, the reference must disclose each and every limitation of the claim to which it is compared. *Schumer v. Laboratory Computer Sys., Inc.*, 308 F.3d 1304 (Fed. Cir. 2002); *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292 (Fed. Cir. 2002). Applicant has amended claim 1 to recite administration of at least 1×10^{10} nucleated cells. In the rejection under 35 U.S.C. § 103(a), below, the Examiner acknowledges that "U.S. '681 does not teach administration of over 5 billion nucleated cells." Office Action at page 8. In the same manner, Boyse does not teach administration of over 500 million stem cells, as recited in amended claim 1. Thus, claim 1, as amended, and all claims depending from claim 1, are not anticipated by Boyse. Applicant therefore requests that the Examiner withdraw the rejection of claims 1-10 and 14-28 on this ground.

The Rejection Under 35 U.S.C. 103(a) Should Be Withdrawn

The Examiner has rejected claims 1-28 under 35 U.S.C. § 103(a) as obvious over Boyse in light of Kondo, Sakabe *et al.* ("Sakabe"), Gluckman *et al.* (1998) ("Gluckman 1998") and Gluckman *et al.* (2001) ("Gluckman 2001"). Applicant respectfully traverses.

To establish a *prima facie* case of obviousness, the Examiner must demonstrate three things with respect to each claim: (1) the cited references, when combined, teach or suggest every element of the claim; (2) one of ordinary skill would have been motivated to combine the teachings of the cited references at the time of the invention; and (3) there would have been a reasonable expectation that the claimed invention would succeed. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991).

The Examiner states that "[a]s described above, U.S. '681 teaches the hematopoietic reconstitution of irradiated mice with blood from fetal and neonatal mice," and cites the ostensible teachings of Sakabe (that blood comprises $CD34^+CD38^+$ and $CD34^+CD38^-$ cells) and Kondo (that blood comprises growth factors). The Examiner does not, however, explain how Boyse renders claims 1-28 obvious, for example, by detailing how the combination of Boyse, Sakabe, Gluckman 1998 and Gluckman 2001 teaches or suggests each of the limitations of the claims, and thus has not made out the required *prima facie* case of obviousness.

Applicant has amended claim 1 to recite that at least 1×10^{10} nucleated cells, or at least 1×10^9 stem cells, are administered to an individual. The Examiner has stated that Boyse does not teach administration of more than 5×10^9 total nucleated cells. Office Action, page 8. Sakabe, Gluckman 1998 and Gluckman 2001, likewise, do not teach or suggest administration of at least 1×10^{10} nucleated cells, or at least 1×10^9 stem cells. The Examiner points only to Gluckman 1998 as teaching that "a high number of transplanted nucleated cells is a good prognostic indicator for a successful procedure." Office Action, page 8. Gluckman, however, makes this statement in the context of delivery of a single unit of cord blood, which Gluckman 1998 teaches comprises a median of 11×10^8 total nucleated cells (in a range of 0.13 to 58×10^8). Gluckman 1998, page 9, right column. Gluckman does not teach the numbers of stem cells contained within a unit of cord blood, but that number is expected to be far smaller because only a small percentage of total nucleated cells in cord blood are stem cells. Thus, Gluckman teaches only the administration of a maximum of 58×10^8 total nucleated cells (and, by implication, a correspondingly smaller number of stem cells).

Given the above, the combination of Boyse, Sakabe, Kondo, Gluckman 1998 and Gluckman 2001 fails to teach or suggest all limitations of the claims of the present application, as amended.

In addition, the Examiner states that "U.S. '681 does not teach treating myelodysplasia or treating patients with the specific conditions recited in claims 14-23 . . ."

Office Action, page 6. The remaining references cited by the Examiner also do not teach or suggest treatment of these conditions. Given the above, the combination of references cited by the Examiner additionally cannot render claims 14-23 obvious.

Moreover, a person of skill in the art would not necessarily conclude that administration of more stem cells is always desirable. Boyse, for example, specifically teaches that *smaller* doses of cord blood or cord blood-derived stem cells are feasible. *See, e.g.*, col. 13, lines 44-48; compare Example 6.11.4 with 6.11.1-6.11.3. Thus, the cited art, as a whole, teaches that higher doses of cord blood, or cord blood-derived stem cells, are not necessary.

Given the above, Applicant submits that the combination of Boyse, Sakabe, Gluckman 1998 and Gluckman 2001 does not render any of claims 1-11 and 13-28, as amended, obvious. Applicant respectfully requests that the Examiner withdraw the rejection of claims 1-11 and 13-28 on this basis.

Conclusion

For the reasons provided above, the claims as amended should now be in condition for allowance, and early notice of the same is earnestly solicited. No new search of the prior art is required to assess patentabilty of the claims. Applicant believes that no fee is due for this Amendment, beyond that authorized in the accompanying documents. However, if a fee should be deemed due, please charge such fee to Jones Day deposit account no. 503013.

Respectfully submitted,

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